

Dockets Management Branch
The Food and Drug Administration
Department of Health & Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

Date: Oct. 23, 1999

Re: 99P-1340/CP 1 — Petition to Have *Eternity eau de parfum* declared "Misbranded"

Dear Sir or Madam:

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's *Eternity eau de parfum* declared "misbranded." I am writing because I fully support this petition and request that the FDA give it careful attention with regard to your regulations 21CFR Sec. 740.1, 21CFR Sec. 740.2, and 21CFR Sec. 740.10. Regulation 21CFR Sec. 740.10 states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning — The safety of this product has not been determined."

As the petition shows, *Eternity* contains toxic ingredients and ingredients whose safety have not been substantiated. There is no warning label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as *Eternity* so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are not aware that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers. When I am exposed to fragrance products I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

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|--|---|---|---|
| <input type="checkbox"/> anaphylaxis/shock | <input type="checkbox"/> double vision | <input type="checkbox"/> incoherence | <input checked="" type="checkbox"/> nausea |
| <input type="checkbox"/> anxiety, restlessness | <input checked="" type="checkbox"/> ear pain | <input type="checkbox"/> incontinence | <input type="checkbox"/> nose bleeds |
| <input checked="" type="checkbox"/> asthma | <input type="checkbox"/> eczema | <input checked="" type="checkbox"/> irritability | <input type="checkbox"/> rashes |
| <input checked="" type="checkbox"/> breathing difficulty | <input checked="" type="checkbox"/> eyes, watery or dry | <input type="checkbox"/> joint aches | <input type="checkbox"/> seizures |
| <input checked="" type="checkbox"/> bronchitis | <input type="checkbox"/> fatigue | <input checked="" type="checkbox"/> laryngitis | <input type="checkbox"/> short-term mem. loss |
| <input checked="" type="checkbox"/> can't concentrate | <input type="checkbox"/> flushing | <input type="checkbox"/> lethargy | <input checked="" type="checkbox"/> sinusitis |
| <input checked="" type="checkbox"/> coughing | <input checked="" type="checkbox"/> headaches | <input checked="" type="checkbox"/> lymph nodes swell | <input checked="" type="checkbox"/> sneezing |
| <input type="checkbox"/> depression | <input checked="" type="checkbox"/> heart beat irregularity | <input type="checkbox"/> mood swings | <input type="checkbox"/> sores, skin/mouth |
| <input checked="" type="checkbox"/> disorientation | <input type="checkbox"/> hives | <input type="checkbox"/> muscle pain/weakness | <input checked="" type="checkbox"/> swallowing difficulty |
| <input checked="" type="checkbox"/> dizziness | <input type="checkbox"/> hypertension | <input checked="" type="checkbox"/> nasal congestion | <input type="checkbox"/> tinnitus |
| <input type="checkbox"/> other: _____ | | | |

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

Barry E. Sullins (BARRY SULLINS)

C405

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